

Exhibit B

Evidence-Based Evaluation of Inferior Vena Cava Filter Complications Based on Filter Type

Steven E. Deso, MD¹ Ibrahim A. Idakoji, MD, MPH¹ William T. Kuo, MD¹

¹Division of Vascular and Interventional Radiology, Stanford University Medical Center, Stanford, California

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Address for correspondence Steven E. Deso, MD, Division of Vascular and Interventional Radiology, Stanford University Medical Center, 300 Pasteur Drive, H-3651, Stanford, CA 94305 (e-mail: sdeso@stanford.edu).

Abstract

Many inferior vena cava (IVC) filter types, along with their specific risks and complications, are not recognized. The purpose of this study was to evaluate the various FDA-approved IVC filter types to determine device-specific risks, as a way to help identify patients who may benefit from ongoing follow-up versus prompt filter retrieval. An evidence-based electronic search (FDA Premarket Notification, MEDLINE, FDA MAUDE) was performed to identify all IVC filter types and device-specific complications from 1980 to 2014. Twenty-three IVC filter types (14 retrievable, 9 permanent) were identified. The devices were categorized as follows: conical ($n = 14$), conical with umbrella ($n = 1$), conical with cylindrical element ($n = 2$), biconical with cylindrical element ($n = 2$), helical ($n = 1$), spiral ($n = 1$), and complex ($n = 1$). Purely conical filters were associated with the highest reported risks of penetration (90–100%). Filters with cylindrical or umbrella elements were associated with the highest reported risk of IVC thrombosis (30–50%). Conical Bard filters were associated with the highest reported risks of fracture (40%). The various FDA-approved IVC filter types were evaluated for device-specific complications based on best current evidence. This information can be used to guide and optimize clinical management in patients with indwelling IVC filters.

Keywords

- IVC filters
- nonthrombotic complications
- interventional radiology

CME Objective: Upon completion of this article, the reader should be able to distinguish the various retrievable and permanent IVC filter designs, and explain the most common complications associated with the various designs.

Accreditation: This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of Tufts University School of Medicine (TUSM) and Thieme Medical Publishers, New York. TUSM is accredited by the ACCME to provide continuing medical education for physicians.

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The use of inferior vena cava (IVC) filters has dramatically increased over the past three decades in the United States, and the number of filter insertions doubled between 1998 and 2008.^{1,2} By 2012, an estimated 259,000 IVC filters were placed in the United States alone,³ coinciding with a growing number of Food and Drug Administration (FDA)-approved devices. Consequently, the increasing variety of filters along with rising overall use has resulted in increased complications from indwelling IVC filters; this prompted the FDA to issue a safety alert urging all physicians caring for patients with indwelling filters to consider removing the filter as soon as protection from pulmonary embolism (PE) is no longer needed.⁴ Despite this recommendation, many devices are not adequately followed for removal, and the large number of filter types now encountered on routine imaging has made proper device identification difficult. The purpose of this study was to evaluate the various FDA-approved IVC filter designs to determine device-specific risks, as a way of

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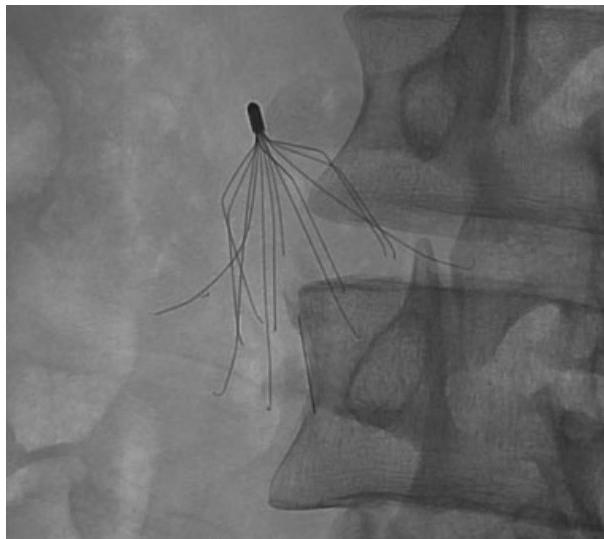


Fig. 1 Fluoroscopic image showing a G2 filter with multiple fractured components.



Fig. 3 Axial CT image showing a 12F Stainless Steel Greenfield filter in place complicated by component perforation (arrow).

helping to identify patients who may benefit from ongoing follow-up or prompt filter retrieval.

Materials and Methods

Identification of IVC Filter Types

The FDA Premarket Notification Database⁵ was searched electronically to identify all IVC filters receiving 510(k) clearance (product code DTK—filter, intravascular, cardiovascular) between 1980 and 2014.

Classification of Filter Complications

IVC filter complications were classified according to the Society of Interventional Radiology (SIR) guidelines⁶ as follows:

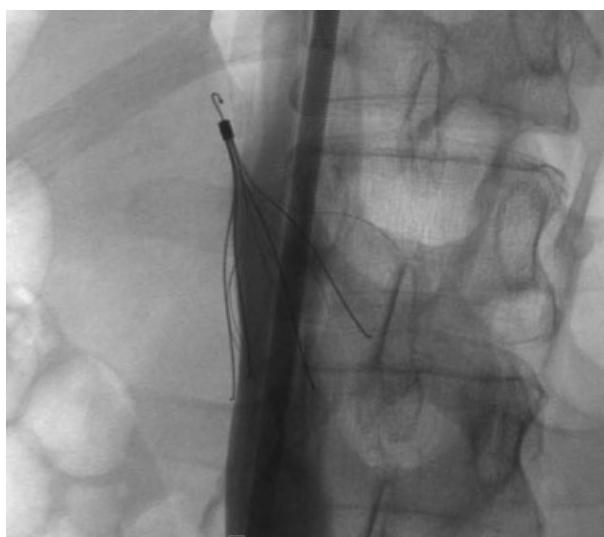


Fig. 2 Fluoroscopic images showing a severely tilted and tip embedded Celect filter.

Fracture: Breakage or separation of any filter component due to structural failure.⁶ The fractured components can remain in situ or undergo distal embolization (**►Fig. 1**).

Insertional problems: Malfunctions in filter deployment including tilting of the filter more than 15 degrees from the IVC axis, incomplete opening, and prolapse of filter components⁶ (**►Fig. 2**).

IVC perforation: Visualization of one or more filter components extending greater than 3 mm beyond the caval wall or into an adjacent structure⁶ such as the duodenum, aorta, psoas muscle, kidney, or vertebral body. Grading schemes defining the degree of perforation have been described in the literature⁷ (**►Fig. 3**).

Migration: Movement of an IVC filter greater than 2 cm along the IVC beyond the initial placement position.⁶ Filter migration may result in filter embolization into the right atrium, right ventricle, or pulmonary arteries (**►Fig. 4**).

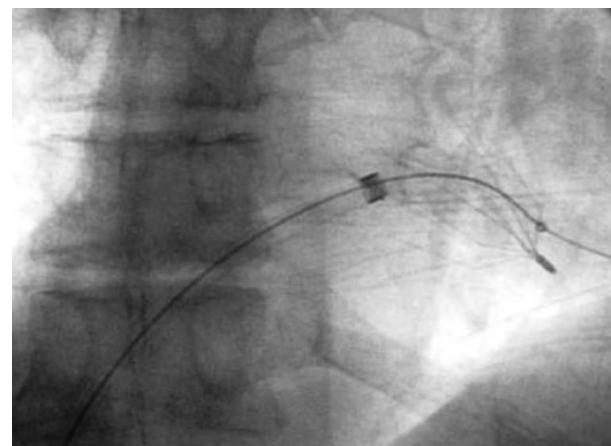


Fig. 4 Fluoroscopic image demonstrating an IVC filter that has migrated into the right ventricle.



Fig. 5 Coronal CT image showing a Bard filter (open arrow) in place with acute thrombotic occlusion of the IVC (solid arrow).

IVC occlusion: Acute or chronic thrombotic occlusion of the IVC following filter placement⁶ (►Fig. 5).

Evidence-Based Search of Filter Complications

An electronic MEDLINE search was performed using the following index search terms: "IVC filter" OR "inferior vena cava filter" OR "ALN filter" OR "Bard Eclipse" OR "Bard G2" OR

"Bard G2X" OR "Bard Recovery" OR "Bard Denali" OR "Bard Meridian" OR "Simon Nitinol" OR "Vena Tech LGM" OR "Vena Tech LP" OR "Greenfield filter" OR "Bird's Nest filter" OR "Celect filter" OR "Günther Tulip" OR "Optease" OR "Trapeze" OR "Safeflo" OR "Option filter" OR "Crux vena cava filter." The results were filtered for English language, clinical trial study type, human species, and date range from 1980 to 2014 (►Fig. 6). All potentially relevant articles were collected for analysis. The references within these articles were reviewed to obtain additional relevant articles for analysis. A data extraction form was used to record the following information: filter type, retrieval rate, complications, and frequency of complications per filter type. Two reviewers verified the accuracy of all data prior to analysis. The FDA Manufacturer and User Facility Device Experience (MAUDE) database⁸ was queried electronically (1992–2014) to identify additional adverse events associated with IVC filter use (product class –filter, intravascular, cardiovascular).

Results

Twenty-four IVC filters were identified. From this group, the Edwards Mobin-Uddin device was excluded as it was removed from the market in 1986.⁹ From the remaining group, nine filters cleared for permanent use, and 14 filters cleared for retrievable or permanent use, were identified (►Table 1). The device distribution based on geometry was as follows: conical ($n = 15$), conical with umbrella ($n = 1$), conical with cylindrical element ($n = 2$), biconical with cylindrical

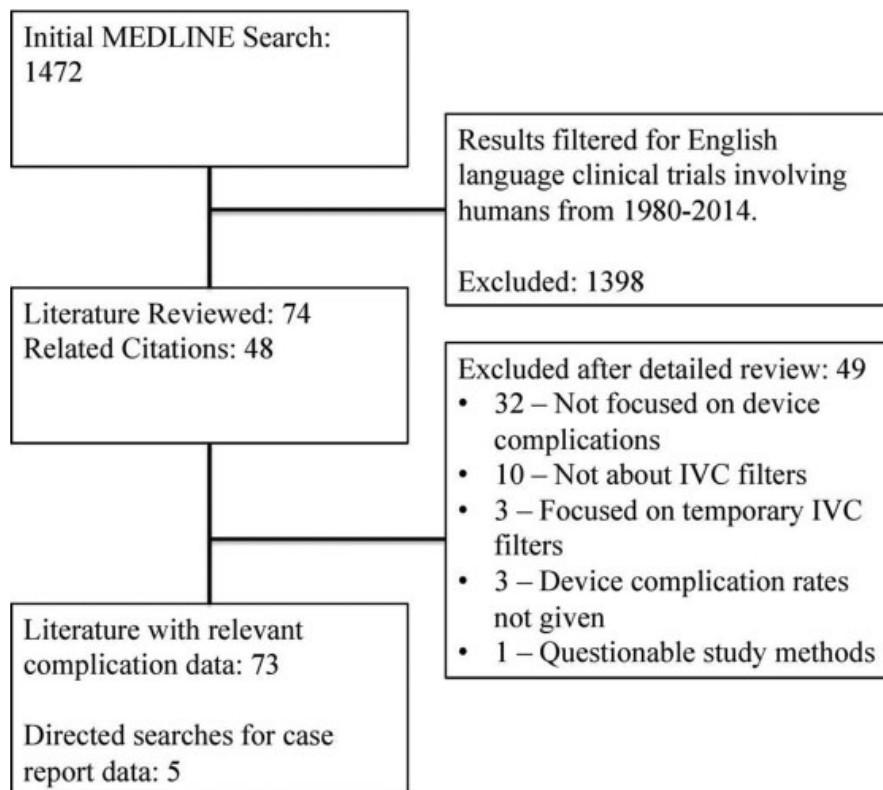


Fig. 6 Literature screening flowchart.

Table 1 IVC Filters in the United States (1980–2014)

Permanent filters	Retrievable filters ^a
<ul style="list-style-type: none"> • 24F stainless steel Greenfield (Boston Scientific, Natick, MA)^b • 12F stainless steel Greenfield (Boston Scientific) • Titanium Greenfield (Boston Scientific) • Vena Tech LGM (B. Braun Medical, Bethlehem, PA)^b • Vena Tech LP (B. Braun Medical) • Trapease (Cordis Endovascular, Warren, NJ) • Bird's Nest (Cook, Bloomington, IN) • Simon Nitinol (Bard Peripheral Vascular, Tempe, AZ) • SafeFlo (Rafael Medical Technologies, Dover, DE)^b 	<ul style="list-style-type: none"> • ALN (ALN International, Miami, FL) • Recovery (Bard Peripheral Vascular)^b • G2 (Bard Peripheral Vascular)^b • G2X (Bard Peripheral Vascular)^b • Eclipse (Bard Peripheral Vascular)^b • Meridian (Bard Peripheral Vascular)^b • Denali (Bard Peripheral Vascular) • Günther Tulip (Cook) • Celect (Cook)^b • Celect Platinum (Cook) • Optease (Cordis Endovascular, Warren, NJ) • Option (Argon, Plano, TX)^b • Option Elite (Argon, Plano, TX) • Crux (Volcano, San Diego, CA)

^aAll retrievable filters are also approved for permanent use.

^bNo longer manufactured but may still be encountered from prior implantation.

element ($n = 2$), helical ($n = 1$), spiral with umbrella ($n = 1$), and complex ($n = 1$) (►Fig. 7).

Reported device-specific complications were identified among all filter types, and the highest reported complications for each device are summarized in ►Table 2. The risk of complications was found to vary widely depending on the specific IVC filter type.

Fracture

Early conical Bard Peripheral Vascular (Tempe, AZ) filters were associated with the highest reported rates of fracture. The fracture rate for the original Bard Recovery device was 5.5 to 25% with an estimated incidence of 39.5% at 65.7 months.^{10–14} The fracture rate for the Bard G2 devices (G2, G2X, Eclipse, Meridian) was initially 1.2 to 12%, but the highest reported rate was later found to be 38% at 60 months.^{11,13,15,16} High fracture rates were also reported

for the Simon Nitinol filter (Bard) (10–16%)^{17,18} and the Optease/Trapease (Cordis, Miami Lakes, FL) (up to 50%).¹⁹

Insertional Issues

Filter tilting greater than 15 degrees during insertion were reported among the following conical filters: Bard Recovery (2.3–15%),^{20,21} Bard G2/G2X/Eclipse (14–18%),^{15,22,23} Cook (Bloomington, IN) Günther Tulip (11.5–24%),^{24–27} 24F Greenfield (Boston Scientific, Marlborough, MA) (7–12%),^{28,29} 12F Stainless Steel Greenfield (Boston Scientific) (9.9–55%),^{30,31} and Titanium Greenfield (Boston Scientific) (8.3–41%).^{30,32,33} In addition, wire prolapse up to 70% was reported for the Cook Bird's Nest filter.³⁴

Inferior Vena Cava Perforation

Purely conical filters were associated with the highest reported rates of IVC perforation and were reported as follows: Bard Recovery (27–100%),^{12,14} Bard G2/G2X/Eclipse (26–44%),^{15,23} Bard Simon Nitinol (25–95%),^{17,18} Cook Günther Tulip (22–78%),^{7,35–37} Cook Celect (22–93%),^{7,35,38,39} and Titanium Greenfield (prior to hook modification) (13–50%).^{40,41} In addition, IVC strut perforation up to 85% was reported for the Cook Bird's Nest filter.³⁴

Migration

Migration rates greater or equal to 10% were reported among the following devices: Bard Recovery (0–10%),^{10,12,20} Bard G2 (12–25%),^{15,20} Titanium Greenfield (7.5–15%),^{33,42} Cook Günther Tulip (2.4–12.5%),^{26,36,43} and Vena Tech LGM (6–18.4%).^{33,44,45}

Inferior Vena Cava Occlusion

Filters with a cylindrical component (Vena Tech LGM, Trapease/OptEase) or umbrella element (Simon-Nitinol) were associated with high rates of caval thrombosis. The highest reported rate of IVC occlusion for the Trapease/OptEase filters was 28.6%.⁴⁶ The rates of chronic IVC occlusion with the Simon Nitinol filter range from 3.5 to 50%,^{17,47–49} and for the VenaTech LGM, the IVC occlusion rate is as high as 65% at 9 years.⁴⁵

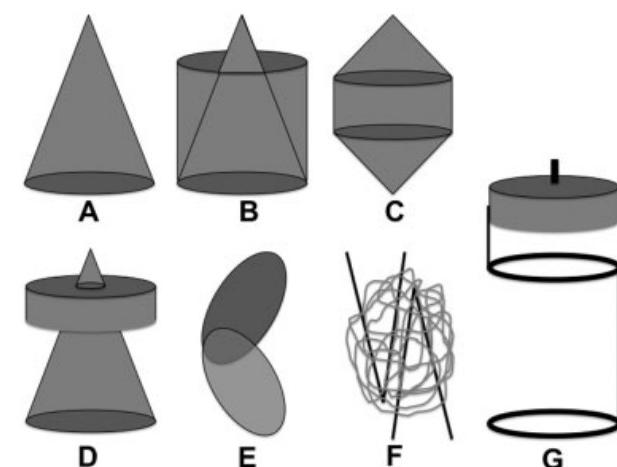


Fig. 7 IVC filter geometries: (A) conical, (B) conical with cylindrical element, (C) biconical with cylindrical element, (D) conical with umbrella, (E) helical, (F) complex, (G) spiral with umbrella.

Table 2 Highest reported radiographically identifiable complications for each filter type

Device (year FDA cleared)	Fracture	IVC perforation	Migration	IVC occlusion
ALN (2008)	Case reports (0%) ^{54–56}	3.4% (3.4%) ⁵⁴	3% (1.4–3%) ^{57,58}	Case reports (0%) ^{54,58,59}
Recovery (2003/2005 ^a)	39.5% at 65.7 mo 25% (5.5–25%) ^{10–14}	100% (27–100%) ^{12,14}	10% (0–10%) ^{10,12,20,21}	Case reports (0%) ¹⁴
G2 (2005/2008) G2X (2008) Eclipse (2008) Meridian (2011)	38% at 60 mo 12% (1.2–12%) ^{11,13,15,16,23,60}	44% (18–44%) ^{15,23,60,61}	25% (12–25%) ^{15,20,23}	2.2% (0–2.2%) ^{22,60}
Denali (2013)	Case reports ⁶²	2.5% (2.5%) ⁶³	Limited data	Limited data
Simon Nitinol (1990)	16% (10–16%) ^{17,18}	95% (25–95%) ^{17,18}	5% (0–5%) ^{18,47}	50% (3.5–50%) ^{17,47–49}
LGM/Vena Tech LGM (1989)	Case reports ⁶⁴	Case reports (0%) ^{44,65}	18.4% (6–18.4%) ^{33,44,45,66}	65% at 9 y (3.7%/y) ⁴⁵
Vena Tech LP (2001)	Limited data	Case reports (0%) ⁶⁷	Case reports (0%) ⁶⁷	Limited data
24F SS Greenfield (1973)	Case reports ⁶⁸	15% (2–15%) ^{69,70}	2% (2%) ⁶⁹	5% (2–5%) ^{28,29,71,72}
12F SS Greenfield (1995)	0.3% (0.3%) ⁷³	1% (1%) ⁷³	2.6% (2.6%) ⁷³	12% (5–12%) ^{31,74}
Titanium Greenfield (1989)	3.8% (3.8%) ⁷⁴	50% (13–50% prior to hook modification, 1% with MH design) ^{40,41}	15% (7.5–15%) ^{33,42}	20% (3.5–20%) ^{32,75}
Günther Tulip (2000/2003 ^a)	0.3% (0.3%) ³⁶	78% (22–78%) ^{7,35–37}	12.5% (2.4–12.5%) ^{26,36,43}	4.1% (2.4–4.1%) ^{36,43}
Celect (2007/2008 ^a) Celect Platinum (2012)	5.6% (4.3–5.6%) ^{39,76}	93% (22–93%) ^{7,35,38,39}	4.3% (0–4.3%) ^{38,76,77}	2.5% (2.5%) ³⁸
Bird's Nest (1989)	4% (3–4%) ⁴¹	85% (85%) ³⁴	1.1% (1.1%) ⁷⁸	4.7% (2.9–4.7%) ^{34,78}
Optease (2002/2004 ^a) Trapease (2000)	50% (0–50%) ^{19,79–84}	Case Reports (0%) ^{79,83,84}	0.9% (0–0.9%) ^{79–81,83,84}	29% (0.8–29%) ^{46,79,83–86}
Option (2009)	Limited data	10% (2.9–10%) ^{37,87}	2% (2.9%) ⁸⁷	4% (4%) ⁸⁷
Crux (2012)	Limited data (0%) ⁸⁸	Limited data	Limited data (0%) ⁸⁸	Limited data (7.2% nonocclusive IVC thrombus) ⁸⁸

Abbreviations: FDA, Federal Drug Administration; IVC, inferior vena cava.

Note: For the SafeFlo filter (2009), no significant clinical data are available, and the device is no longer manufactured.

^aSubsequent year when filter was cleared for retrieval indication.

Discussion

Over the past few decades, IVC filter use has risen in the United States,^{1,2} which has led to increased recognition of a wide range of potential filter-related complications. These complications include fracture, IVC perforation, component embolization, device migration, and IVC occlusion. In response to rising complication rates, the current FDA Safety Alert on IVC filters recommends filter removal when protection from PE is no longer needed. More recently, the FDA released an additional Safety Communication stating that the risk-to-benefit ratio begins to favor IVC filter removal within 29 to 54 days after implantation, if the risk of PE has passed.^{50,51}

The systematic review by Angel et al⁵² concluded that filter complications are a serious concern associated with long-term filter use, but the study did not address device-specific risks, and there was no analysis specifically of complications from permanent IVC filters. A large variety of retrievable and permanent IVC filters are commonly encountered on routine imaging studies, but the myriad number of filter types and their associated complications prevents interpretation of such radiographic findings. Filter-related complications may therefore go unrecognized or underappreciated as potential causes of morbidity in patients, including those presenting with intractable abdominal pain from filter penetration.⁵³

The goal of this study was to evaluate the various FDA-approved IVC filter designs to determine device-specific risks, and to help identify patients who may benefit from ongoing follow-up versus prompt filter retrieval. First, we identified the 23 filter types currently encountered in the United States. Next, the complications associated with each filter type were identified. Although we initially searched the FDA MAUDE database, we soon realized these data were based on voluntary reporting and there was gross underreporting of complications. Therefore, we chose to use evidence-based methods to identify the highest reported complication rates in the literature for each filter type (►Table 2).

These data revealed a high risk of fracture among Bard and Cordis (Miami Lakes, FL) IVC filters, including a fracture incidence of 39.5% at 65.7 months with the Bard Recovery device,^{10–14} a 38% risk of fracture at 60 months among the Bard G2 type filters,^{11,13,15,16} and a 50% risk of fracture with Cordis Optease/Trapease devices.¹⁹ A high risk of IVC perforation was reported with the Bard Recovery and Cook Celect filters, with penetration rates exceeding 90% for both.^{7,12} For permanent filter types, a high risk of IVC occlusion was reported among the Simon Nitinol and Vena Tech LGM⁹ filters with occlusion rates of 50 and 65% (at 9 years),^{45,49} respectively. Overall, as these complications appear to be related to filter geometry, one should always assess for IVC perforation, when a conical device is identified, and IVC occlusion, when a cylindrical or umbrella filter component is identified.

This study is limited by the quality of available data on IVC filters, and some filter types in this study were limited published data. In addition, many studies had limited long-term follow-up; therefore, it is possible that the true risk of

complications for these filter types could be even higher than currently reported, as complications tend to increase after longer dwell times. Nevertheless, mitigation against these effects was attempted by identifying the highest complication rates reported so far in the literature. Future studies should involve methods to provide constant updating of filter complication rates as new data emerge in larger cohorts.

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